

ENDIUS.061A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Alan E. Shluzas
Appl. No. : 10/075,668
Filed : February 13, 2002
For : APPARATUS FOR
CONNECTING A
LONGITUDINAL MEMBER TO
A BONE PORTION
Examiner : Anuradha Ramana
Group Art Unit : 3732

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DECLARATION OF ALAN E. SHLUZAS PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Alan E. Shluzas, do declare as follows:

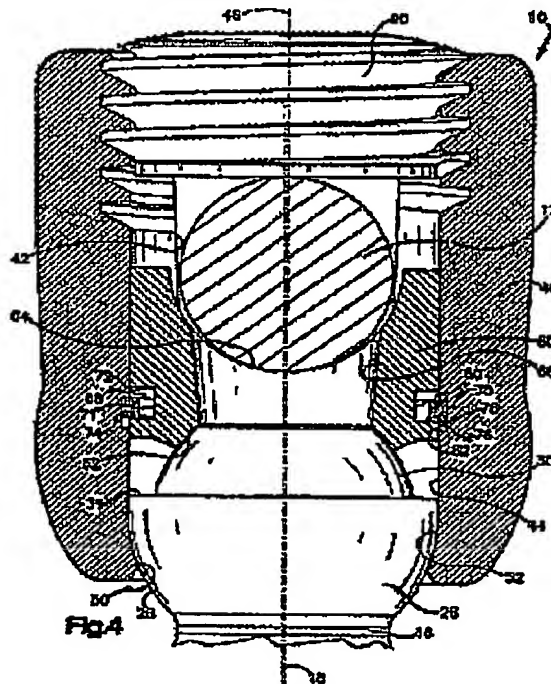
1. I am a United States citizen, and I reside at 297 Temple St., #302, West Roxbury, Massachusetts 02132.
2. I am currently Principal Engineer at Endius Incorporated, 23 West Bacon Street, Plainville, Massachusetts 02762 ("Endius"). I have worked at Endius since September 1999.
3. I have a degree from Northeastern University.
4. I am the inventor of the subject matter claimed in U.S. Patent Application No. 10/075,668, filed February 13, 2002 (the '668 application).
5. I have personal knowledge of the following facts and if called upon as a witness to competently testify thereto, I could and would do so.
6. The '668 application describes and claims an apparatus that can be used to connect a longitudinal member to a portion of a bone, such as a pedicle of a vertebra. In one embodiment, referring to Figure 4 of the '668 application reproduced below, the longitudinal member may be a fixation rod 12, which sits within a first passage 42 of a housing 40 on a spacer 60 positioned within the housing. The spacer 60 engages a part spherical head 30 of a fastener

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16, the fastener extending into the housing 40 through a second passage 44 which is transverse to the first passage 42. This apparatus is configured to prevent relative movement between the fastener 16 and the housing 40 and to hold the longitudinal axis of the fastener in any of a plurality of desired angular positions relative to the longitudinal axis of the second passage when the longitudinal member is disengaged from the spacer and the spacer engages the fastener. (See e.g., Claim 1 as amended) Advantageously, the surgeon is thus able to manually move the housing 40 relative to the fastener 16 to a desired position, but upon ceasing such movement, the fastener and the housing maintain their positions relative to one another.



7. The above-described apparatus of the '668 application specifically overcomes problems with prior art bone anchors, such as the bone anchor described in U.S. Patent No. 6,485,491 to Farris et al. (the Farris patent), which I have reviewed along with certain other patents cited in this application.

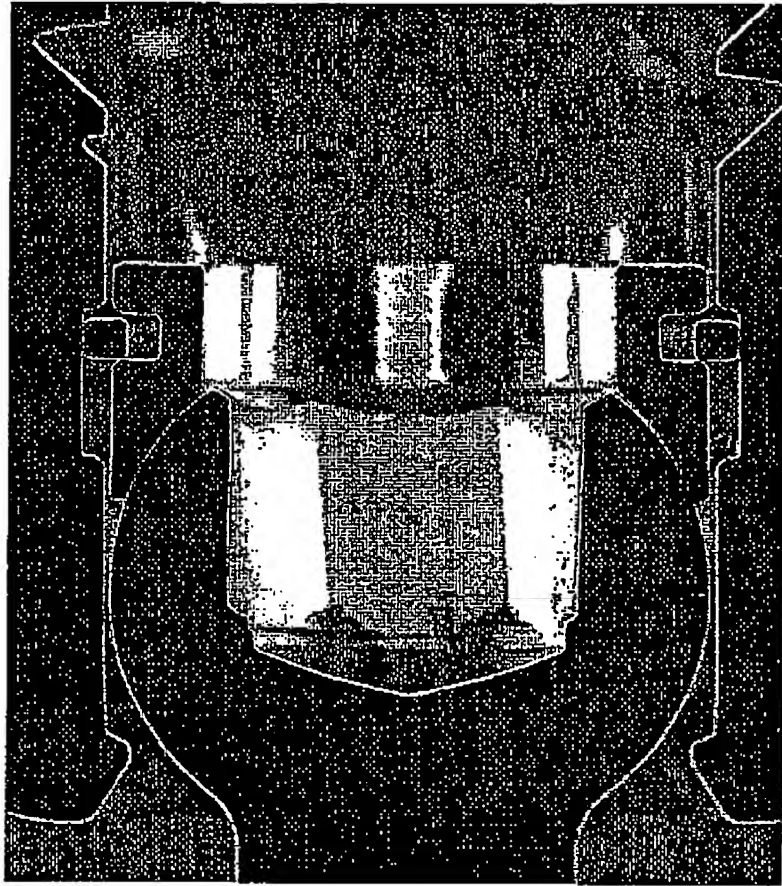
8. The Farris patent discloses, in connection with Figure 53 reproduced below, a multi-axial bone anchor assembly 262 that includes a saddle member 22d, a bone anchoring member 24a, and a washer 26d.

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member is disengaged from a spacer. I also do not believe that the Farris patent teaches an arrangement where a spacer necessarily engages a fastener when a longitudinal member is so disengaged. For example, in connection with Figure 53, the groove 48d (shown in Figure 54) is shown and described as having a thickness much greater than the thickness of the snap ring 28. This construction permits a separation between the washer 26d and the bone anchoring member 24a of at least about one-half the thickness of the groove 48d when the washer-and-snap ring assembly is slid to the top of the groove 48d and the bone anchoring member 24a is at the bottom position, abutting a surface at the bottom end of the channel 34d. Even if the structure of Figure 53 used a non-planar snap ring 28' as described at column 7, lines 32-43 of the Farris patent, I still do not believe that such a structure would produce the advantageous result described in ¶ 6 above. This is particularly true because the Farris patent shows in Figure 53 that the groove 48d should be about four times the thickness of the snap ring, yet the non-planar snap ring 28' is only disclosed as being large enough to fill a greater, but not an entire, portion of the groove so as to allow less play between saddle member, anchoring member and washer.

11. These beliefs were confirmed by my review of a product called the CD HORIZON® VERTEX® Multi-Axial Screw, sold by Medtronic Sofamor Danek, Inc. ("Danek"), which I understand is an affiliate of SDGI Holdings, Inc., the owner of the Farris patent according to assignment records now available at the United States Patent Office. I obtained samples of these screws and obtained a cross-section of one of the screws. The photograph below was taken of the cross-sectioned screw.

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12. I believe that the internal structure of the CD HORIZON® VERTEX® Multi-Axial Screw is substantially the same as the internal structure of the bone anchor assembly 262 described in the Farris patent in connection with Figure 53. I therefore believe that the CD HORIZON® VERTEX® Multi-Axial Screw is essentially the commercial embodiment of the assembly described in the Farris patent.

13. I have examined the CD HORIZON® VERTEX® Multi-Axial Screw, and the CD HORIZON® VERTEX® Multi-Axial Screw does not prevent relative movement between a fastener and a housing and does not hold a longitudinal axis of the fastener in any one of a plurality of desired angular positions relative to a longitudinal axis of a passage in the housing. I believe that the screw lacks this feature at least in part because when a longitudinal member is disengaged from a spacer, the spacer does not necessarily engage the fastener. Rather, when the fastener sits within the housing of the CD HORIZON® VERTEX® Multi-Axial Screw and a

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longitudinal member is disengaged, the washer and the snap ring are free to slide to the top of the groove in the housing forming a substantial gap between the washer and the fastener, permitting the fastener to freely move about relative to the housing.

14. I further believe that other embodiments described in the Farris patent do not disclose or suggest preventing relative movement between a fastener and a housing and holding a longitudinal axis of the fastener in any one of a plurality of desired angular positions relative to a longitudinal axis of a passage in the housing when a longitudinal member is disengaged from a spacer and the spacer engages the fastener. For example, the Farris patent in another embodiment relates to a posterior fixation system that includes a multi-axial bone anchor assembly 20, illustrated in Figure 1, reproduced below. The bone anchor 20 is described in the Farris patent as having a saddle member 22, a bone anchoring member 24, and a washer 26. The saddle member 22 has a channel 34 that receives a rod 36. A snap ring 28 extends into a groove in the saddle member 22. I do not believe that the snap ring 28 would necessarily prevent relative movement between the saddle member 22 and the bone anchoring member 24 and hold a longitudinal axis of the bone anchoring member in any one of a plurality of desired angular positions relative to a longitudinal axis of a passage in the saddle member when the rod 36 is disengaged from the washer 26. Nor do I believe that this embodiment of the Farris patent teaches or suggests such a result.

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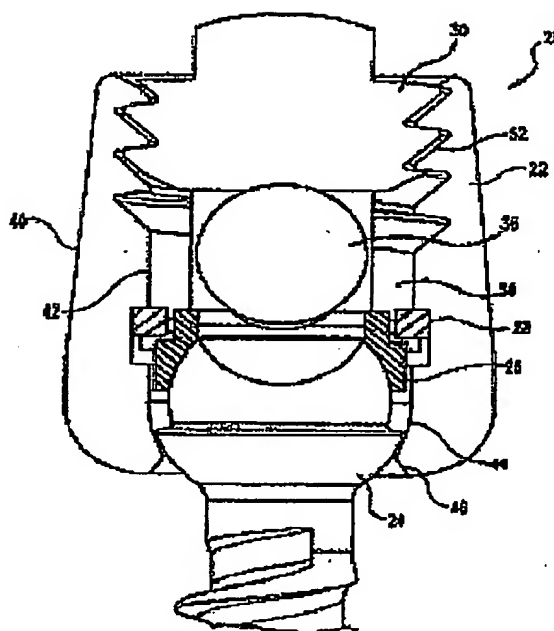


Fig. 1

15. A snap ring 28' is described in connection with Figure 17a (reproduced below) of the Farris patent that has a non-planar construction. The snap ring 28' is said to reduce the play between the saddle member 22, the anchoring member 24, and the washer 26 because the non-planar snap ring fills a greater portion of the groove 48 in the saddle member. See column 7, lines 32-43 of the Farris patent. Similar to my statements in ¶ 10 above, I do not believe that the snap ring 28' would necessarily prevent relative movement between the saddle member 22 and the bone anchoring member 24 and hold a longitudinal axis of the bone anchoring member in any one of a plurality of desired angular positions relative to a longitudinal axis of a passage in the saddle member when the rod 36 is disengaged from the washer 26. Nor do I believe that such an arrangement is obvious in view of this embodiment of the Farris patent, or any of Farris' teachings or suggestions.

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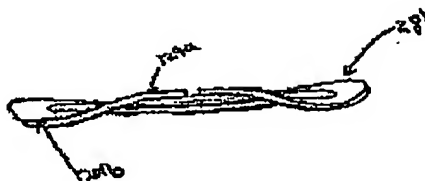


FIG. 17a

16. First, the non-planar snap ring 28' is said to only produce "less play" (see Col 7, L. 39) between the saddle member 22, anchoring member 24 and the washer 26. It is my opinion that "less play" means there must be "some play" among those members and, therefore, the design of the Farris patent teaches away from the design of the '668 application. There must be "no play" in order to prevent relative movement among these components and to hold the housing or saddle member in any one of a desired plurality of angular positions relative to the anchoring member or fastener. Farris does not teach or suggest "no play" but rather teaches "some play."

17. Furthermore, the explanation given in the Farris patent for producing "less play" makes it clear to me that it is not a design that prevents relative angular movement, or a design which renders the latter obvious. At Col. 7, LL 42-43, the Farris patent explains that "less play" results from a design in which the snap ring 28' "fills a greater portion of groove 48 of saddle member 22." Such a design does not yield an arrangement in which relative movement between the saddle member and the anchoring member is prevented. The groove 48 is an indentation or groove in the saddle member and is shown in Fig. 3. The fact that the snap ring 28' fills a greater portion of such groove does not mean that there is any contact with or engagement between the snap ring and the washer 26. In fact, Fig. 1 shows spaces between those members and there is no description or suggestion that there is relative engagement. Spaces are also shown between the washer and the anchoring member. There are also other lines surrounding the snap ring 28 which are impossible for me to decipher, making the design of the Farris patent very difficult to interpret.

18. The one thing that is taught by Farris is that there is "less play" among these members and therefore some play. In my opinion, the Farris design does result in some play because there is no teaching or suggestion that the snap ring 28' engages the groove 48 on the housing and the upper surface 83 of the washer 26 (see Fig. 9) and that it is compressed in such

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space, thereby providing an axially downward force sufficient to prevent relative movement among the pertinent members.

19. This arrangement is what is now being claimed in Claim 1 (as amended) as follows:

(Currently Amended) An apparatus for connecting a longitudinal member with a bone portion comprising:

[a longitudinal member connectable with a bone portion;]

a fastener having a longitudinal axis and engageable with the bone portion to connect said longitudinal member to the bone portion;

a housing having a first passage configured to receive said longitudinal member, said housing having a second passage with a longitudinal axis extending transverse to said first passage, said fastener extending through an opening in said housing into said second passage and being movable relative to said housing, said longitudinal axis of said fastener being positionable in any one of a plurality of desired angular positions relative to said longitudinal axis of said second passage, the second passage having a horizontal indentation;

a spacer received in said second passage of said housing and engageable with said fastener and said longitudinal member and having a radial surface below said indentation; and

a member engaging both the horizontal indentation in the second passage and the radial surface of the spacer that applies an axial force to the spacer to preventing relative movement between said fastener and said housing and holding said longitudinal axis of said fastener in any one of said plurality of desired angular positions relative to said longitudinal axis of said second passage when said longitudinal member is disengaged from said spacer and said spacer engages said fastener, said fastener and said housing being manually movable relative to each other against said force when said longitudinal member is disengaged from said spacer and said member applies said force. [;

a clamping mechanism that clamps said longitudinal member, said spacer and said housing to said fastener to prevent movement of said fastener relative to said housing.]

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20. It is my opinion that the foregoing claim is nonobvious in view of Farris and its teachings and suggestions. Furthermore, it is my opinion that the commercial embodiment of the fastener covered by the foregoing claim has been a commercial success. Over a period of about two years, sales of such a fastener were approximately \$3,000,000 - \$4,000,000.

21. Therefore it is my opinion that at least Claim 1 as recited above is nonobvious in view of the Farris patent, either alone or in view of the other prior art I have reviewed.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 3/22/05


Alan E. Shluzas

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